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Initial Experience with a New Method of External Polyester Scaffolding for Infrainguinal Vein Grafts

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Abstract *Objectives:* This study aims to evaluate the feasibility of external polyester scaffolding in infrainguinal bypass grafting when available vein material is suboptimal due to varicosity or dilatation. Primary objectives were short-term primary patency, assisted primary patency and secondary patency. Secondary objectives were to assess the rate of graft stenoses, infections and other adverse effects related to the use of external scaffolding.
Materials and methods: A total of 50 consecutive patients were included in this prospective, multicentre, feasibility study from six centres. The indication for infrainguinal bypass was critical limb ischaemia (64%), severe claudication (34%) or popliteal aneurysm (2%). Indications for the use of the external scaffolding were varicosity of the vein graft, ectatic vein graft or the use of spliced vein grafts with segments of widely differing diameters. Duplex scanning of the graft was done perioperatively and at follow-up visits at 1, 3, 6 and 12 months after operation.
Results: Primary patency, assisted primary patency and secondary patency at 6 months were 82.3% (±SE 6.2%), 88.6% (±SE 4.8%) and 92.1% (±SE 4.4%), respectively. Six graft stenoses were detected in duplex surveillance. There were no infections related to polyester mesh.
Conclusions: External scaffolding of infrainguinal vein grafts may be a promising innovation. Early results from this multicentre study show that polyester mesh is safe and feasible adjunct to peripheral revascularization enabling the use of otherwise non-optimal vein grafts with acceptable short-term patency.

Autologous vein is considered to be superior to prosthetic grafts as bypass material for infrainguinal reconstructions in terms of long-term patency and resistance to infections. Klinkert et al.[1] reviewed the literature and concluded that saphenous vein is the graft of choice for infra- and supra-popliteal bypasses if only available and of acceptable

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quality. Autologous veins other than greater saphenous vein have also been shown to be superior compared to prosthetic grafts especially for infrapopliteal revascularizations.[2–4] Unfortunately, autologous veins are occasionally of non-optimal quality due to small-calibre, varicosities or post-phlebitic changes. Varicosity is usually a contraindication to autologous vein bypass because of increased formation of intimal hyperplasia, the risk of aneurysm formation and even grafts rupture. Arm veins are often thin walled and their diameter is large especially at proximal portions. Therefore, they can be liable to long-term dilatation.[5]

External polyester mesh tube provides external support for autologous vein grafts of compromised quality and limits postoperative dilatation of the vein graft in the dramatically different haemodynamics of the arterial system. The use of external support has been proposed to allow the use of non-optimal quality veins otherwise unacceptable for bypass grafting. External mesh is supposed to stabilise the vein, and thus minimise the arterial stress with the objective of reducing the rate of stenosis and therefore improve patency. Numerous preclinical animal studies employing external support of autologous suboptimal-quality vein bypasses have shown a less-pronounced neointima formation as the underlying cause for significantly improved long-term patency rates compared to unsupported grafts.[6–9] Moreover, several small clinical series have shown that both polytetrafluoroethylene (PTFE) and polyester prosthetic reinforcement of varicose vein grafts can be used with acceptable results.[10–17]

The aim of this study was to evaluate the feasibility and short-term outcome of external polyester mesh tube in infrainguinal bypass procedures when available vein material is of non-optimal quality. The primary objective was to assess short-term primary, assisted primary and secondary patencies. Secondary objectives were to evaluate the severity of intimal thickening of grafts during follow-up, infection rate and other complications and practical problems related to the use of external scaffolding.

Material and Methods

This study was a prospective, multicentre, observational pilot study. In the Helsinki University Central Hospital, 20 patients were included from May 2005 to March 2008. At the same time, in five German centres a similar study was started, which included 30 patients. The data from all six centres with a total of 50 patients were combined. Participating centres were: Helsinki University Central Hospital, Finland (20 patients); Johannes Gutenberg University Hospital Mainz, Germany (13 patients); J.W. Goethe University Hospital, Frankfurt, Germany (12 patients); Municipal Hospital Muehldorf, Germany (three patients); Verbundkrankenhaus Bernkastel/Wittlich, Wittlich, Germany (one patient) and Kath. Kliniken Essen-Nord, Essen, Germany (one patient).

Informed consent

Informed consent was obtained from all patients before they entered the study. The nature, purpose and risks of the study were explained, and the patients were provided with a copy of the patient information sheet. The study protocol was approved by ethics committee and the Institutional Review Board of Helsinki University Central Hospital.

Patient inclusion and exclusion criteria

Patients included had to be suitable for bypass operation with overall health status permitting vascular surgery and anaesthesia with adjunctive medications. Indication for surgery was critical limb ischaemia with rest pain or a non-infected ulcer or severe claudication resistant to conservative treatment. One patient was operated for a popliteal aneurysm (Table 1). In all patients, the quality of vein material was suboptimal due to varicosities or ectatic dilatation. There were small differences between participating centres concerning vein-quality criteria. In Germany only patients with varicotic vein grafts were included whereas in Finland also patients with ectatic (diameter >8 mm) arm veins and patients with spliced vein grafts with at least one ectatic segment were included. Exclusion criteria were grossly infected gangrene in the affected limb and life expectancy less than 1 year which would have excluded follow-up visits. Patients were also excluded if they were unable to understand the full meaning of the informed consent.

Description of the polyester mesh product

The polyester mesh tube (ProVena®, B. Braun Aesculap, Germany) is manufactured from multifilament polyester

Table 1 Characteristics of patients undergoing vein bypass with external polyester scaffolding.

Characteristic	$n = 50$	%
Age, median (range)	72 (39–93)	
Body mass index (bmi), median (range)	27.0 (20.0–39.0)	
Male gender	34	68
Coronary artery disease	24	48
Diabetes	21	42
Renal insufficiency (creatinine >120 μmol/l)	9	18
Hypertension	40	80
Hyperlipidemia	27	54
Current smoking	13	26
Indication[a]		
Claudication	17	34
Ischaemic rest pain	6	12
Ulcer or gangrene	26	52
Popliteal aneurysm	1	2
Preoperative medication		
Aspirin	29	58
Clopidogrel	7	14
Warfarin	10	20

[a] CLI as indication: Helsinki 17/20; Mainz 5/13; Frankfurt 8/10; Mühldorf 1/3; Essen 0/1; Wittlich 0/1.

yarn (polyethylene terephthalate) and supplied in various diameters and lengths. ProVena® is an open porous prosthesis with honeycomb-like structure for intra-operative external scaffolding of autologous veins. The desired length of the tube network is drawn over the autologous vein and it adapts to the vein configuration irregularities.

Clinical evaluation

Clinical evaluation including medical history, inspection of the limb status and vascular laboratory assessment (ankle-brachial indices (ABIs) and toe pressure measurements) was performed in all patients before bypass operation. The suitability of arterial anatomy for bypass was evaluated by magnetic resonance angiography (MRA) or conventional digital subtraction angiography (DSA). The vein graft was preoperatively evaluated by duplex scanning (i.e., vein mapping).

Procedure

Vascular surgeons experienced in the diagnosis and treatment of lower limb ischaemia performed the operations. Conforming to hospital routine, prophylactic antibiotics were administered to all patients as if they were receiving a prosthetic bypass. Infrainguinal bypass with autologous vein was performed according to the preference of the operating surgeon. The operating surgeon decided whether the vein graft was to be used in reversed or non-reversed position. If spliced vein graft was used, reversed or non-reversed vein segments were employed to minimise size mismatch of vein-to-vein anastomoses and artery-to-vein anastomoses. The vein-to-vein anastomoses were sutured with 7/0 interrupted sutures. Prior to suturing the arterial—vein anastomoses, an appropriate length of polyester mesh tube was drawn over the vein graft with a specially designed instrument. Generally, fibrin glue was used to fix the mesh to the outer layer of vein graft to facilitate anastomosis suturing if the mesh tube was extended to cover one or both anastomoses (Fig. 1A and B). At the end of the procedure a transit time measurement was used to ensure adequate graft flow, and intra-operative duplex scanning was performed to exclude graft segments of inappropriate quality and technical defects in anastomoses. If the duplex scanning was not performed intra-operatively, it was performed postoperatively before discharge. Completion angiography was not routinely performed.

Additional vascular procedures

All additional vascular procedures including graft revisions and angioplasties of the bypassed extremity during follow-up were registered. Wound revisions, skin grafts and minor amputations were not considered to be additional procedures in this study.

Follow-up

There were some differences concerning the surveillance programmes between participating centres. In Helsinki, follow-up visits were at 1(—2), 6 and 12 months after operation. All five German centres had follow-up visits at 1, 3 and 6 months postoperatively. At each follow-up visit the evaluation protocol was the same, including inspection of the limb status, measurement of ankle-brachial indices (ABIs) and toe pressures and duplex scanning of the entire graft. The velocity ratio (*Vr*) over 3.0 or the peak systolic velocity (PSV) over 300 cm s^{-1} was used as threshold value for significant graft stenosis.

Data collection and statistical analyses

Clinical data was collected at patient enrolment, at the time of the procedure, at discharge and at planned follow-up visits. Data were collected using patient record forms. Kaplan—Meier method was used to calculate primary, assisted primary and secondary patencies. SPSS for Windows, version 16.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses.

Results

Median age of the study population was 72 years. Two-thirds of patients (68%) were male. Almost half (48%) of the patients had coronary artery disease. The incidence of diabetes was 42%. The study population had also a number of other concurrent diseases (Table 1). One patient had thrombophilia (antiphospholipid antibodies), which had previously been diagnosed after deep venous thrombosis. Thirty-four (68%) vein grafts consisted of a one-piece saphenous vein, the rest were spliced vein grafts (Table 2). The outflow artery

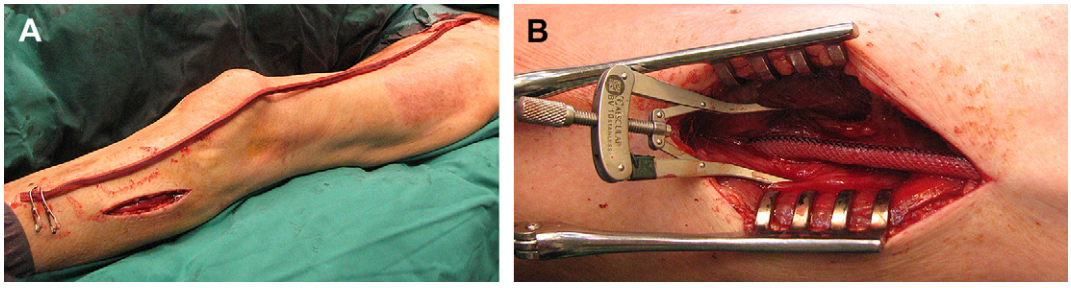

Figure 1 (A) Proximal anastomosis and vein-to-vein anastomosis are completed and polyester mesh is drawn over the spliced arm vein graft (B) Distal anastomosis of a femoral-to anterior tibial artery bypass is completed.

Table 2 Operative details of bypass surgery with externally supported vein grafts.

	n	%
Inflow artery		
Common femoral artery	39	78
Superficial femoral artery	5	10
Deep femoral artery	1	2
Proximal popliteal artery	3	6
Distal popliteal artery	1	2
Graft (limb of aortofemoral graft)	1	2
Outflow artery		
Proximal popliteal artery	9	18
Distal popliteal artery	17	34
Anterior tibial artery	8	16
Posterior tibial artery	6	12
Peroneal artery	9	18
Pedal artery	1	2
Vein graft material		
GSV (single piece)	34	68
Spliced vein (two pieces)		
GSV + GSV	5	10
GSV + SSV	3	6
GSV + ceph	2	4
GSV + bas	1	2
Ceph + bas	2	4
Spliced vein (three pieces)		
GSV + GSV + SSV	1	2
GSV + GSV + ceph	1	2
Ceph + ceph + bas	1	2
Vein graft configuration		
Reversed	21	42
Non-reversed	25	50
Both (spliced vein grafts)	4	8
Polyester mesh		
Length (cm), median (range)	40 (10–70)	
Diameter (mm), median (range)	6 (4–8)	

GSV = great saphenous vein; SSV = short saphenous vein; ceph = cephalic vein; bas = basilic vein.

was popliteal artery in 52% of patients and the most common infrapopliteal outflow artery was the peroneal artery (18%) (Table 2). The indication for the use of external scaffolding was varicosity (60%) or ectatic dilatation of the graft or at least one of the vein segments in spliced vein graft (40%).

Primary, assisted primary and secondary patencies with standard errors (SEs) at 6 months were 82.3% (SE ± 6.2%), 88.6% (SE ± 4.8%) and 92.1% (SE ± 4.4%), respectively (Fig. 2). A total of six graft stenoses were detected under duplex surveillance. Two of them were <50% stenoses (*Vr* < 2.0–3.0) outside the scaffolded part of the graft detected 3 months after operation. These stenoses did not require balloon angioplasty. One stenosis exceeding 50% (*Vr* 3.0–4.0) in the middle of the graft and another over 50% stenosis in the proximal part of the graft required balloon angioplasty. There was also one 75% (*Vr* > 4.0) mid-graft stenosis, which was treated endovascularly. One high-grade stenosis (*Vr* > 7.0) above the scaffolded segment was

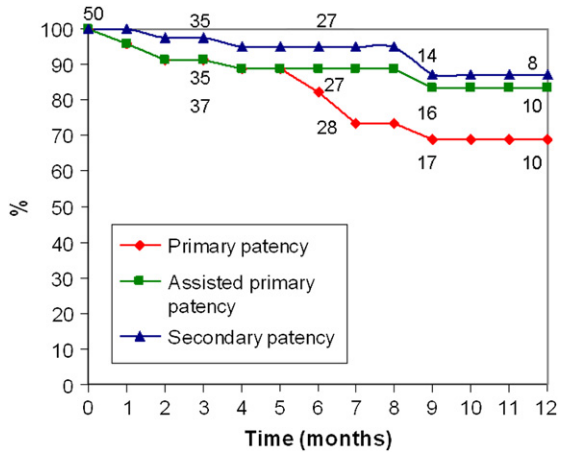

Figure 2 Cumulative primary patency, assisted primary patency and secondary patency. Numbers indicate grafts at risk. Standard error (SE) was <10% throughout the time interval.

treated with interposition. The only immediate failure occurred on the third postoperative day and was treated by thrombectomy and patch angioplasty of distal anastomosis. There were four graft occlusions at 2, 4, 5 and 9 months, postoperatively, all but one without limb loss. The graft occlusion at 5 months postoperatively led to below-knee amputation 1 month later. This patient received the bypass for critical limb ischaemia. One patient with crural ulcers and former aorto-bi-femoral prosthesis was maintained on long-term antibiotics. One patient had postoperative cellulitis in the operated limb but negative ultrasonography and scintigraphy ruled out the infection of the polyester mesh. Thus, there were no severe infections related to polyester mesh tube.

In a subgroup of patients with critical limb ischaemia, survival and limb salvage at 1 year were 88.2% (SE ± 6.4%) and 90.0% (SE ± 6.7%), respectively. In addition to the amputation due to graft occlusion and persisting ischaemia, another major amputation was performed due to persistent gangrene despite of patent bypass 6 months after revascularization.

Five patients were lost to follow-up, one after discharge from hospital and four others at 1, 5, 12 and 13 months postoperatively. The median follow-up time was 7 months (range: 0–36 months).

Completion angiographies, though not used routinely, confirmed uniform vessel configurations even in vein grafts that were originally heavily varicotic (Fig. 3A–C).

Discussion

The idea of scaffolding the vein grafts is not new. External reinforcement of normal vein graft with a polyester graft was first described in 1963.[10] Melliere et al.[11] reported on a small series of patients with critical limb ischaemia whereby dilated segments of greater saphenous veins were wrapped in short segments of PTFE prosthesis or hand-made polyester mesh. Neufang et al.[14] reported over 80% secondary patency rates at 1 year for PTFE-reinforced varicotic vein grafts in infrainguinal bypass surgery.

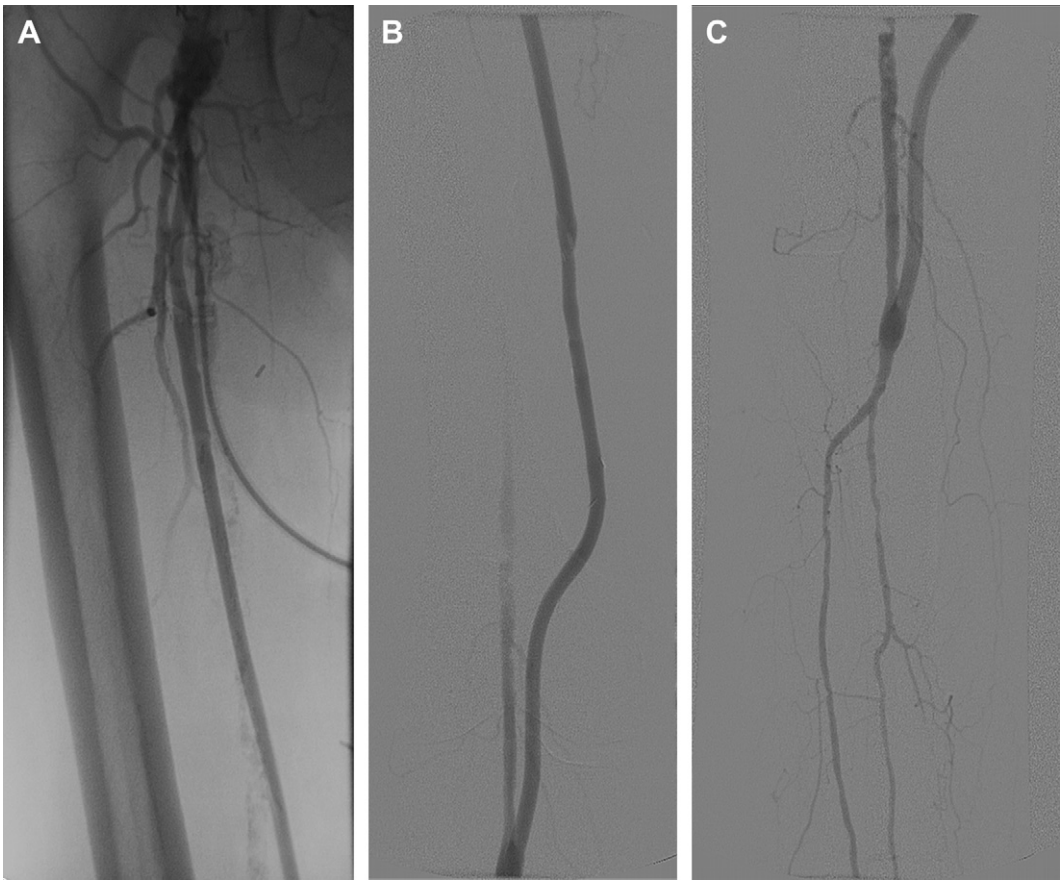

Figure 3 (A—C) Postoperative angiography of originally heavily varicotic greater saphenous vein graft with diameter difference from 4 to 12 mm after implantation of polyester mesh tube of 5 mm diameter.

Recently Mellière et al.[15] concluded that patency rates using varicotic vein grafts with prosthetic reinforcement are higher than those achieved using prosthetic grafts. They also found that reinforced vein graft zones did not develop stenosis and unreinforced zones developed little or no dilatation.

Although it has been demonstrated in several animal studies that external support reduces intimal hyperplasia, the ideal scaffolding material has yet not been identified. According to a recent study,[18] external stenting with macro-porous polyester mesh reduced neointimal hyperplasia more effectively than PTFE and other commercially available stents possibly due to better circumferential compliance. In our series, the same kind of macro-porous material was used.

In infrainguinal vein bypasses the incidence of focal stenoses due to intimal hyperplasia is 20—35% within 1—2 years after operation.[19—23] Arm vein grafts are especially prone to development of stenosis and aneurysm.[5] The incidence of vein graft abnormalities after arm vein bypass has been reported to be as high as 55%.[5] In our series, 12% of these non-optimal vein grafts developed stenosis within 6 months. There were no aneurysms of vein grafts.

In this study, two-thirds of patients were operated due to critical limb ischaemia. Patency rates in this series are comparable to results of previous studies by others where prosthetic reinforcement of the vein grafts was used.[10—17] Furthermore, secondary patency at 1 year resembled those reported in large series of good-quality infrainguinal venous bypasses for critical limb ischaemia without graft reinforcement.[24] Vein graft material used in this series was non-optimal, and therefore our results can be considered to be acceptable compared to results obtained from other series.[25] Primary patency at 6 months in our series was 82.3%, but assisted primary and secondary patencies were significantly better, which emphasises the importance of vein graft surveillance. Duplex surveillance seems to be especially important in arm vein grafts. Armstrong et al.[5] found that duplex surveillance resulted in a 49% intervention rate after arm vein bypass.

Apart from the use on varicotic grafts, the external scaffolding is probably most beneficial in arm veins, in heavily dilated vein grafts and in spliced vein grafts with segments of different sizes. One advantage of polyester mesh is that it secures side-branch clips even during graft tunnelling. Furthermore, when polyester mesh is correctly in place, it aids in avoiding twisting of the graft during tunnelling. In cases were a thin-walled arm vein is sutured to a long arteriotomy after femoral endarterectomy, the polyester mesh provides the required support. On the other hand, the use of external scaffolding necessitates more equipment and makes the procedure more complex and time consuming. Disruption of the valves of totally covered non-reversed vein grafts is more difficult as valve pockets are no longer visible. However, this problem can be handled by initial covering of only a short segment of the proximal

graft, while the rest is covered after completion of the proximal anastomosis and valve lysis. Especially when the graft diameter is normalised in post-phlebitic veins or the cephalic vein including antecubital portion, severe thickening of the vein wall and intraluminal pathology should be ruled out by intra-operative evaluation to avoid stenosis of the graft. The polyester mesh, as a synthetic material, can be prone to infections, especially when used in ischaemic limb with potentially infected tissue. Generally, infection rates after infrainguinal prosthetic bypasses are reported to range from 1% to 6%.[26,27]

Results of this study indicate that the use of external polyester scaffolding for varicose or dilated vein grafts is safe. There was one infection which was not directly related to the polyester mesh. Other adverse effects were not observed in this series. Possible limitations of this feasibility study are the lack of a control group and a rather short follow-up time. The study population is also quite heterogeneous due to some differences in indications for polyester mesh use between participating centres.

In conclusion, polyester mesh is safe and feasible adjunct to infrainguinal bypass using suboptimal autologous vein grafts with no harmful effects observed in this study. However, larger prospective series and longer follow-up time will still be needed to prove its safety. In order to prove a benefit with respect to incidence of vein graft stenosis and graft patency, randomised controlled trials comparing polyester scaffolded vein grafts with non-scaffolded ones and with prosthetic bypass material are obviously needed. External scaffolding may enable the use of vein grafts of compromised quality.

Conflict of Interest

B. Braun has supported study centres by covering some extra costs connected to this study. Anders Albäck and Mauri Lepäntalo have received a travel grant from B. Braun for presenting early results of this study.

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